

ing, Section 502 (a), the label statement, "Each Tablet Contains * * * Orchic Substance . . . 0.05 Gram," was misleading since it failed to reveal the material fact that orchic substance possesses no therapeutic activity when taken by mouth.

Further misbranding, Section 502 (e), the product was fabricated from two or more ingredients, and its label failed to bear a statement of the quantity or proportion of strychnine contained in the product; and, Section 502 (f) (2), the label failed to bear adequate warnings against use of the article in those pathological conditions wherein its use may be dangerous to health, and against unsafe duration of administration, since the label failed to warn that, in view of the yohimbine hydrochloride present, it should not be taken by those suffering from heart disease, high blood pressure, or kidney disease; the label also failed to warn that an article containing nux vomica may be dangerous, especially when used by elderly persons; and it also failed to warn that use of a product containing yohimbine hydrochloride should be discontinued if stomach disturbance, nausea, vomiting, vertigo, or fainting occur.

DISPOSITION: August 29, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1807. Misbranding of Testox Tablets. U. S. v. 129 Bottles and 142 Bottles of Testox Tablets. Default decree of condemnation and destruction. (F. D. C. No. 16650. Sample No. 456-H.)

LIBEL FILED: June 28, 1945, Northern District of Georgia.

ALLEGED SHIPMENT: On or about April 2, 1945, by the Veltex Co., from Birmingham, Ala.

PRODUCT: 129 20-tablet bottles and 142 100-tablet bottles of *Testox Tablets* at Atlanta, Ga. Examination of samples showed that the product had the composition declared upon its label.

LABEL, IN PART: "Textox 20 [or "100"] Tablets Distributed by Copy Boy Sales Co., * * * Atlanta 3, Ga. Each Tablet Contains: Vitamin B₁ . . . 666 U. S. P. Units Yohimbin Hydrochloride . . . 0.0005 Gram Orchic Substance . . . 0.05 Gram Calcium Glycerophosphate . . . 0.15 Gram Sodium Glycerophosphate . . . 0.15 Gram Extract Nux Vomica . . . 0.03 Gram."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following label statements created the false and misleading impression that the product would be effective as a sex restorer, whereas it would not be effective in producing such a result: "Textox * * * Directions—Take 2 to 3 Tablets depending upon age and severity of case * * * When desired effect is reached discontinue use"; and the label statement, "Each Tablet Contains * * * Orchic Substance . . . 0.05 Gram," was misleading since it failed to reveal the material fact that orchic substance possesses no therapeutic activity when taken by mouth.

Further misbranding, Section 502 (e) (2), the product was a drug fabricated from two or more ingredients, and its label failed to state the quantity of strychnine it contained; Section 502 (f) (2), the label of the product failed to warn that, in view of the presence of yohimbine hydrochloride in the product, it should not be taken by persons suffering from heart disease, high blood pressure, or kidney disease; and the label also failed to warn that an article containing nux vomica might be dangerous, especially when used by elderly persons, and that the use of a product containing yohimbine hydrochloride should be discontinued if stomach disturbance, nausea, vomiting, vertigo, or fainting occur.

DISPOSITION: August 1, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1808. Misbranding of World's Bitter Tonic. U. S. v. 164 Cartons of World's Bitter Tonic A Laxative and Stomachic Medicine. Default decree of condemnation and destruction. (F. D. C. No. 17098. Sample No. 2782-H.)

LIBEL FILED: August 8, 1945, District of Maryland.

ALLEGED SHIPMENT: On or about April 21 and June 26, 1945, by World's Medicine Co., from Columbus, Ohio.

PRODUCT: 164 cartons, each containing 1 bottle, of *World's Bitter Tonic* at Baltimore, Md. Analysis showed that the product consisted essentially of extracts of plant drugs, including laxative plant drugs, strychnine 0.0025 grain per fluid ounce, sugar, saccharin, an iron compound, salicylates, benzoates, alcohol, and water.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label designation "Bitter Tonic" was false and misleading since, in order to derive benefit from a bitter tonic, it should be used regularly over an extended period, and the article, by reason of its laxative properties, was not suitable for such use; Section 502 (e) (2), the label failed to bear a statement of the quantity or proportion of strychnine in the article, since the label statement, "containing .038 grains of strychnine alkaloid per fluid oz.," was incorrect; Section 502 (f) (1), the article was represented as a stomachic, and the labeling failed to bear adequate directions for use as such; and, Section 502 (f) (2), the labeling failed to bear adequate warnings against unsafe methods or duration of administration of the article, since it failed to warn that, when taken frequently or continuously, as was provided by the directions, such use may result in dependence upon laxatives to move the bowels.

DISPOSITION: September 13, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1809. Misbranding of an unlabeled drug. U. S. v. 1,944 Bottles of an Unlabeled Drug. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 16713. Sample No. 4166-H.)

LIBEL FILED: July 26, 1945, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about April 25, 1945, from Camden, N. J., by the Aid Laboratories.

PRODUCT: 1,944 unlabeled 3-ounce bottles of a drug consisting of a solution of epsom salt, iron chloride, a small proportion of a citrate, and a trace of quinine in glycerin and water, at Philadelphia, Pa.

NATURE OF CHARGE: Misbranding, Section 502 (b), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and it failed to bear an accurate statement of the quantity of the contents; Section 502 (e) (2), it was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient; and, Section 502 (f), the article was essentially a laxative, and its labeling failed to bear any directions for use; and it also failed to warn that the article should not be taken in case of nausea, vomiting, abdominal pain, or other symptom of appendicitis, and that frequent or continued use of the article may result in dependence upon laxatives to move the bowels.

DISPOSITION: October 11, 1945. The Union Drug Co., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond for labeling under the supervision of the Federal Security Agency.

1810. Misbranding of BF-1 Tablets. U. S. v. 598 Bottles and 16 Bottles of BF-1 Tablets, and 5,000 leaflets. Default decree of condemnation and destruction. (F. D. C. No. 16712. Sample Nos. 27842-H, 27843-H.)

LIBEL FILED: August 18, 1945, Western District of Washington.

ALLEGED SHIPMENT: Between the approximate dates of June 23, 1944, and April 2, 1945, by the Vegetrates Co., from Los Angeles, Calif.

PRODUCT: 598 100-tablet bottles and 16 450-tablet bottles of *BF-1 Tablets*, and 5,000 leaflets entitled "Vegetrates," at Seattle, Wash. Examination showed that the product consisted of ground plant material, including senna, alfalfa, starch, Irish moss, dulse, yeast, and parsley.

NATURE OF CHARGE: Misbranding, Section 502 (a), the words "Average Ration," borne on the bottle label, and certain statements in the leaflets, were misleading since they represented and suggested that the article was a food, whereas it was not a food, but a laxative drug; and the following statements in the leaflet were false and misleading since a senna laxative is not capable of producing the benefits claimed: "Use Vegetrates BF-1 and Live, Work, Play Every Day. Don't let restless nights spoil your tomorrows. That glorious feeling of waking up each morning ready to start the day with a song! No putting off appointments, turning down 'dates,' neglecting work because you are 'all in,' have a headache, or feel bad. You, too, can enjoy the sparkling, vibrant freshness each morning by being 'regular.' When that slightest feeling of heaviness, or that 'clogged up' feeling comes, try Vegetrates BF-1, used as directed on label."

Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against unsafe methods or duration of administration, since the warning appearing on the label, "do not use a laxative continuously as there is a possibility of it becoming habit forming," had been made